

## REMARKS

Favorable reconsideration of this application as presently amended is respectfully requested. Claims 1-18 are pending. No new matter is added.

Claims 1, 5, 7 15-16 and 18 are rejected under 36 U.S.C. 102(b) as being anticipated by EP0369292 A1 to Rothgang *et al.* The Examiner states that Rothgang contains a fine powdered urea prior to the addition of the water. Rothgang also requires that a buffer to be added to the reagent mixture. Claim 1 has been amended to read that the first composition containing the urea is buffer free. Support for this amendment is found at page 3, line 16-17; page 11, lines 2 – 14.

Claim 1 has also been amended to clarify the properties of the system vs. the intended use of the system. In the currently pending claim 1 of the instant invention, it states that the first composition has the property of coating the sample with only the moisture inherent in the sample. This is feature is not found in the Rothgang patent where it is taught that the dry reagent mixture is either compressed into a tablet or placed in a capsule; both of which are activated by added water at the time of testing.

It is further taught in the pending application that the quantity of urea, or urea/anti-caking agent, mix is in the range of 5 to 50 mg and optimally 30 mg of fine powder. (Pg. 12, lines 15-16) In the Rothgang patent it is taught that between 10 to 320 mg of urea is mixed with .01 to 1 mg buffer and up to 50 times the volume of the urea/buffer combination in inert extender. (Pg. 6, lines 9 – 15, pg 7, line 21) The inert extender is needed to make the compressed product a manageable size to handle, preferably 30 mg. (Pg. 8, line 22) Although the Rothgang patent teaches a wide range of weight, it is submitted that the preferred embodiment of 30 mg would contain very little urea and, once diluted, the ratio of urea to other ingredients would be reduced further, as would the accuracy. It is submitted that the use of the fine powder and the direct contact with the urea by the specimen, increases testing accuracy.

It is therefore respectfully submitted that the fact that the urea composition of the instant invention has the ability to coat the sample without the addition of water eliminates Rothgang *et al* as a reference against Claim 1.

Claims 5 and 7 are dependent upon Claim 1. Applicant is not patenting phenol red as an indicator but rather phenol red being used as the indicator in the novel system of Claim 1.

Likewise, applicant is not claiming the use of two containers, but rather the compositions of Claim 1 isolated into two containers.

Further Claims 5 and 7 directly from claim 1, and, accordingly, include all of the patentable features of claim 1 as well as other patentable features. Therefore, claims 5 and 7 are patentable over Rothgang *et al* for at least the reasons discussed above with respect to claim 1.

Claims 15-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Rothgang *et al*. Claim 15, wherein it states that the powdered composition can consist of urea and an indicator has been amended to state that the composition has the properties that enable it to coat the sample and indicate the presence of urease using only the moisture inherent in the sample.

Again, in the Rothgang *et al* patent although the indicator can be mixed with the urea/buffer combination, water is required to activate the process. It is therefore submitted that with the amendments to Claim 15, the Rothgang *et al* rejection is overcome.

Claim 16 has been amended to state that the composition, rather than just the urea, has a mean particle size of less than 0.1 mm. Claim 16 is dependent upon claim 15 and therefore is only applicable to the unique composition of claim 15. Claim 18 refers to the indicator containing a pH indicator that changes color at a certain pH level. This is not novel in of itself; however applicant is claiming this as a limitation to the independent claim 15 and not as an independent patentable feature.

Further, claims 16 and 18 depend directly from claim 15, and, accordingly, include all of the patentable features of claim 15. Therefore, claims 16 and 18 are patentable over Rothgang *et al* for at least the reasons discussed above with respect to claim 15.

Claims 1, 7-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by either U. S. Patent 4,585,623 to Chandler or U.S. Patent 4,690,801 to Anderson.

Chandler teaches the use of a powdered urea in a device for performing chemical or immunochemical assays. As the Chandler patent is directed to the actual device, there is little teaching regarding urea other than it is maintained in a dry powdered state until an aqueous solution is introduced into the tube. Again, as in the Rothgang patent, a liquid is used to activate the process and the dry state is used to maintain purity until use.

The Anderson patent is another apparatus used for performing quantitative or qualitative assays. The device contains several reservoirs, the third of which contains two compartments

separated by a frangible seal. The urea is maintained in one of the compartments with a reagent liquid in the other compartment. When the frangible seal between the two compartments is broken, the urea and reagent liquid mix and, upon the rupturing of a second frangible seal, flow into and through the tubes.

Again, as in the Rothgang and Chandler patents, the urea is maintained in the dry state until mixed with a liquid immediately prior to use. As stated in the specification and in the foregoing remarks the pending application does not have to use water but rather relies on the inherent moisture within the sample to activate the reagents.

It is respectfully submitted that Claim 1 overcomes this rejection for the reasons stated above. Claim 9 has been amended to state that an anti-caking agent is added to the first composition and that the first composition has a mean particle size to coat the sample using only the inherent moisture. Both the Chandler and Anderson patents mix the powdered urea with a liquid at the time of testing and do not provide any teachings as to how to eliminate the need to add water. In fact, as both the Chandler and Anderson patents refer to devices for the mixing of a powdered substance with a liquid, the exclusion of the requirement for liquid, as in the instant invention, would be contrary to the teachings of the patents.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Chandler or Anderson in view of Rothgang et al. The Examiner states that would have been obvious, in view of the foregoing patents, to use bromothymol blue or phenol red as indicators to show the presence of bacteria indicating ammonia.

It is respectfully submitted that applicant is not patenting bromothymol blue, phenol red or the use of indicators. Applicant is rather patenting a novel testing system, having specific properties, to indicate the presence of ammonia. As claim 12 is a dependent claim, it does not stand patentability wise on its own and obtains its patentability from the corresponding independent claim.

Further, claim 12 depends directly from claim 9, and, accordingly, includes all of the patentable features of claim 9. Therefore, claim 9 is patentable over either of Chandler or Anderson in view of Rothgang *et al* for at least the reasons discussed above with respect to claim 9.

#### Doubling Patenting

The undersigned has filed a terminal disclaimer per the Examiner's request.

If the Examiner has any questions or concerns regarding the present response, the Examiner is invited to contact Sheldon Parker at 703-563-2041.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Sheldon H. Parker".

Sheldon H. Parker  
Reg. No. 20,738

**September 6, 2005**